

Docket No.: **141-446**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
PATENT OPERATION

In re Application of:	)	
	)	
Kositprapa et al.	)	Group Art Unit: 1614
	)	
Serial No.: 10/777,542	)	Examiner: Weddington, Kevin E.
	)	
Filed: February 12, 2004	)	

For: **NOVEL PHARMACEUTICAL FORMULATION CONTAINING A BIGUANIDE AND A THIAZOLIDINEDIONE DERIVATIVE**

New York, New York 10036  
December 22, 2010

Via Electronic Filing System  
Hon. Commissioner of Patents  
P.O. Box 1450

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the duty to disclose under 37 C.F.R. §1.56, enclosed please find Form PTO/SB/08a listing references which may be considered material to the patentability of the claims of the above-identified application.

I hereby certify that this correspondence is being submitted via the Electronic Filing System (“EFS”) to the United States Patent and Trademark Office on December 22, 2010.

/Nicholas P. Chiara/

Nicholas P. Chiara, Reg. No. 52,737

## REMARKS

A copy of the references designated as U.S. Patents (U.S. Pat) 1-3 and U.S. Patent Application Publications (“US Pub”) 1-3 are not being submitted as per 37 C.F.R. §1.98(a)(2)(ii). Copies of the Foreign Patent Documents (“FPD”) 1-5 are being submitted as per 37 C.F.R. §1.98(a)(2)(i).

Because References US Pat 1-3, US Pub 1-3 and FPD 1-4 are in English, Applicants are not submitting Statements of Relevance as per 37 C.F.R. §1.98(a)(3)(i).

Because references FPD 5 is not in English, Applicants are submitting a Statement of Relevance as per 37 C.F.R. §1.98(a)(3)(i) and a translation (attached to FPD 5).

Copies of the references designated as Non-Patent Literature Documents (“NPL”) 1-14 are being submitted herewith under 37 C.F.R. 1.98(a)(2)(i) and (ii). Because References NPL 1-14 are in English, Applicants are not submitting Statements of Relevance as per 37 C.F.R. §1.98(a)(3)(i). Applicants were only in possession of an Abstract for Reference NPL 10, and therefore only the abstract is being submitted herewith.

NPL 1 is a supplemental European Search Report from the European patent application of the parent of the present application. NPL 3 and 4 relate to the International application (PCT/US03/29292) of the parent application (U.S. Serial No. 10/664,803) of the present application. NPL 5 and 6 relate to the International application of the present application (U.S. Serial No. 10/777,542). NPL 7 relates to the International application of a related child application (PCT/US06/09082). NPL 8-14 relate to documents cited in related foreign applications.

### REFERENCE

FPD 5

CN 15882928A

### STATEMENT OF RELEVANCE

This document relates to methods of treatment comprising metformin and pioglitazone, and formulations comprising metformin and pioglitazone. A translation of this application is attached to FPD 5.

This document was recently cited in a related Chinese patent application and Applicants had the translation prepared because no English language equivalent could be found.

It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made of record therein.

Because this Supplemental Disclosure Statement is being filed after a Request for Continued Examination and before the first action on the merits or the mailing of a Notice of Allowance it is our understanding that no fee is required.

Respectfully submitted,

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